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PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Cardiac Valvular Prosthesis

We, RHONE-POULENC S.A., a French Body Corporate of 22 Avenue Montaigne, Paris 8e, France, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

Known cardiac valvular prostheses proposed for replacing defective cardiac valves, both mitral and aortic, have various disadvantages.

For example, ball valves have appreciable inertia and the considerable cross-section of the ball means greatly slows down the flow of the blood in the case of an aortic prosthesis.

On the other hand rocking disc valves have less inertia and appropriately free the aortic orifice, but they cease to function owing to wear.

Butterfly valves, which comprise a generally circular seat and two coupled semi-circular sealing flaps which rock about substantially diametral parallel axes, avoid these disadvantages. In order that the two flaps may not be held together by capillary effect in the fully open position, it has been proposed to add an appropriate wedge which stops the flaps while they still form a dihedron of several degrees. However, this gives rise to the disadvantage that the blood does not circulate well through this dihedron, whereby the risk of thrombosis is increased.

According to the present invention there is provided a cardiac valvular prosthesis comprising a substantially circular ring having an annular valve seat formed on a downstream surface thereof, and on its periphery, a member suitable to receive sutive threads two substantially semi-circular flaps being each pivoted by two pivot pins to said ring to be movable between a closed position by two pivot pins to said ring to be movable between a closed position in which each flap rests on said valve seat and an open position in which each flap is spaced from the valve seat, said flaps being spaced apart from one another in the open position to leave a passage having a width of 0.5 to 5mm.

The valvular prosthesis of the invention has a low inertia and a wide opening, it is free from points of wear which cause it to cease to function and has no badly irrigated zones. The pins may be spaced apart by a distance, calculated as a function of the thickness of the flaps and of the mode of pivotal connection, such that the flaps in the fully open position have between them a gap which is accessible to the blood flow. A gap of 0.5 to 5 mm., and preferably from 1.0 to 1.3 mm., is generally suitable, the actual valve depending upon the size and the function of the prosthesis. For reasons of convenience, it is generally preferable for the pins to be parallel, but they may without disadvantage be at an angle of a few degrees to one another.

In order that appropriate closure may be ensured, the diametral edges of the flaps, when the valve is closed, must be very close together, with a gap between them of at most 0.1 to 0.3 mm. Such a gap permits a reflux which is too small to be troublesome but which is sufficient to prevent stagnation of the blood.

Owing to these various requirements, at least one of the flaps must not pivot at the level of its diametral edge, but at some distance from this edge. This distance may be immediately calculated from the characteristics chosen for the flaps. Of course, there is a limit which must not be exceeded since the surface of the flap comprised between the pivot pin and the external edge must be greater than the surface comprised between the pin and the diametral edge, in order that the blood pressure may rock the flap.

Advantageously, an abutment is provided to stop the flaps before they become parallel, in order that the reflux of the blood in the dihedral angle which they form may facilitate their closure. An angle of 5° to 45° is generally suitable.

The various parts of the prosthesis may be made of any materials which are resistant to blood and are tolerated by the organism. Generally, the seat, the pins and the flaps consist of stainless metal or alloy (for example the material sold under the Trade Mark "Vitallium"), which is advantagously polished, and the member which is suitable to receive suture threads consists of an inert textile braid, e.g. of PTFE, polyethylene terephthalate, or polyacrylonitrile maintained by any appropriate member such as a spring or screw threaded ring at the base of a peripheral groove in the annular member supporting the seat.

In order that the invention may more readily be understood, the following description is given, merely by way of example, reference being made to the accompanying drawings, in which :

FIGURE 1 illustrates one embodiment of valvular prosthesis, according to the invention, as seen in the direction of its downstream face, and in the closed position; and

FIGURE 2 illustrated the same valve in section.

In these Figures, there will be seen a ring comprising a base 1 and a cover 2 together forming a seat 1*a* and a peripheral groove 1*b*, these members being force-fitted and welded at the base of the groove. Two flaps 3 turn about pivots 3*a*, their travel being limited by an arch 4 when they are at an angle of about 25° with respect to one another. A braid 5 consisting of polyethylene terephthalate filaments, and maintained in the groove 1*b* by a collar 6, is provided to receive sutures when the valve is secured in an aorta.

The opening of the seat has a diameter of 20 mm., the opening of the ring has a diameter of 21 mm., and the flaps have a diametral (lateral) clearance along the pivots of about 0.3 mm., which prevents any formation of a narrow groove, in each flap, due to wear, which might cause stoppages, at the points of contact of the flaps with the arch. In the open position, the diametral edge of each flap is situated upstream of the plane of the seat. The ends of the diametral edges of the flaps are therefore recessed at 3*b* in order that they may not be blocked by the seat. The distance between the diametral edges of the flaps is 0.2 mm. at closure and 1.2 mm. at opening, their thickness being 1 mm.

Of course, it is possible to modify various details of such a prosthesis. Thus, the recesses 3*b* of the flaps may be replaced by equivalent recesses in the seat or by simple channels pressed in the seat. The pivots extending from the flaps may be replaced by independent pins or pins supported by the ring, the thickness of the flaps may decrease gradually from the pins, the rocking pins may be outside the plane of the flaps, the arch 4 may be replaced by stops secured to the flaps, the pins or pivots may turn within grooves cut in the base of the cover 2 or in the seat 1*a*, being enclosed when these two parts are assembled, or they may extend through the thickness of the ring, in which case they are rivetted or welded after the positioning of the flaps.

WHAT WE CLAIM IS :—

1. A cardiac valvular prosthesis comprising a substantially circular ring having an annular valve seat formed on a downstream surface thereof, and on its periphery, a member suitable to receive suture threads, two substantially semi-circular flaps being each pivoted by two pivot pins to said ring to be movable between a closed portion in which each flap rests on said valve seat and an open position in which each flap is spaced from the valve seat, said flaps being spaced apart from one another in the open position to leave a passage having a width of 0.5 to 5 mm.

2. A prosthesis according to claim 1, wherein at least one abutment is provided to engage said valve flaps in said open position at a dihedral angle of between 5° and 45°.

3. A prosthesis according to claim 2, wherein said abutment is formed on an arched member mounted on the downstream side of said ring.

4. A cardiac valvular prosthesis constructed and arranged substantially as hereinbefore described with reference to, and as illustrated in the accompanying drawing.

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1 SHEET This drawing is a reproduction of the Original on a reduced scale

Fig.1.

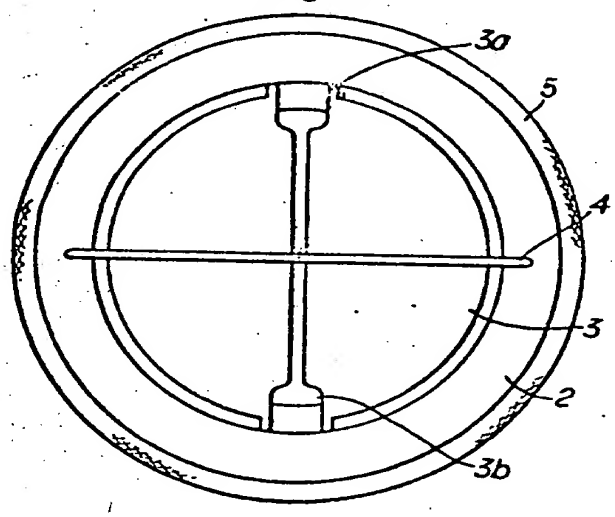

Fig.2.